REMARKS

Reconsideration and allowance of the above referenced application are respectfully requested.

Claims 10-11, 13 and 16-19 stand rejected under 35 USC 102(b) as allegedly being anticipated by Seitz et al., or, in the alternative, under 35 USC 103(a) as allegedly being unpatentable over Seitz et al. in view of *Pulsatile Heart Flow: A Universal Time Scale*" by Gharib et al. (hereinafter "Gharib"). This contention is respectfully traversed.

Initially, Claim 10 defines a series of operations including providing a baseline formation number data, measuring the formation number over time and comparing the measured formation number over time to the baseline data to obtain a differential formation number. Note that these series of claimed operations are more than simply obtaining the formation number. Rather, Claim 10 defines measuring that number over time and making a comparison.

These claims are rejected either over Seitz et al. alone, or Seitz et al. in view of Gharib's teaching about formation numbers. However, nowhere in either of these documents is there any teaching or suggestion of the differential formation number of the type claimed.

As the examiner correctly points out, Seitz et al. teaches a way to determine valve function. This is done through a

series of assumptions, and equations for determining the valve function. According to Seitz et al., the hypotheses were tested based on autopsies of cadavers, see the tables. Nowhere, however, does Seitz have any disclosure, or teaching or suggestion of comparing the areas and pumping capabilities of the heart at one time versus another time to determine differential numbers. In fact, since Seitz used "cadavers", it seems logically inconsistent to consider that Seitz would be able to do that. Certainly, Seitz does not teach using that as indicative of the progress of a valvular dysfunction.

The rejection draws attention to column 2 lines 1-12 which it says describes a baseline. First of all, it is respectfully suggested that the cited section simply discussed quantifying the degree of "stenosis in terms of valvular area". The reference described that alterations in the heart's pumping capability forms a way to diagnose stenosis. See, generally, column 2 lines 21-29 and 39-43. In other words, this describes quantification of the degree of this construction, but teaches nothing about a differential formation number that is indicative of the progress of the valvular dysfunction, as claimed.

In the alternative, the rejection refers to the Gharib article as showing of baseline formation number. While clearly the article did show how the formation number varies with age,

it did not teach or suggest a differential formation number indicative of the progress of valvular dysfunction.

For all these reasons, Claim 10 is wholly different than anything taught or suggested by the prior art, and should be allowable thereover, along with the claims that depend therefrom.

New Claim 22 should be allowable for analogous reasons. Claim 22 further specifies that the formation number is a dimensionless number. This further distinguishes over the Seitz et al. reference which expressly based his analyses on a number of simplifications.

This further distinguishes over Seitz. Seitz makes a number of restricting assumptions in order to reach his conclusions.

This is the list of assumptions that Seitz et al. makes which would result in one not being able to use formation number as a parameter to evaluate the valvular or the ventricular dysfunction.

1.   The flow and pressure across the valve are sinusoidal. This is a major restrictive assumption that is not necessarily correct. It means that Seitz et al.'s results can only apply to sinusoidalily varying pressure and velocity across the valve. This assumption is not correct based on Figure 8 of Seitz et al.'s patent. Waveforms are rectified and this wave form will

not allow Seitz et al. to solve the set of equations and to obtain, for example, equation 1-32. In ours, we do not assume cyclic or sinusoidal variations of pressure or velocity.

2. Seitz et al. assumes that the area of mitral valves is constant during the cardiac cycle. This is not a physiologically observed fact.

3. Seitz et al. assumes that the valve area in different subjects ranges from 1-6 cm. This is a restrictive assumption.

4. Seitz et al. uses a discharge ratio that has been borrowed from non-physiological industrial designs that can only apply to rigid valves with no leaflets.

5. Seitz et al. uses a correction factor that has no proven ground to bring the numbers to some physiologically observed values of area ratios (line 15 of Column 15).

6. Seitz et al. assumes that the temperature and viscosity are constant.

The dimensionless formation number of Claim 22 does not depend on any of these assumptions and are valid for any valve, age, and waveform conditions.

Therefore, Claim 22 should be further allowable on its own merits.

Claim 17 defines using the formation number before operation, intermittently after the operation, and using the differential formation number to indicate the effectiveness of

an operation. There is not one word about this in either Seitz et al. or the Gharib article. Seitz et al. simply describes the methods of determining blood flow within the heart, but says not one word about using this blood flow to determine effectiveness of an operation.

New Claim 23 which is added herein should be allowable for similar reasons to those discussed above with respect to Claim 22.

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicant asks that all claims be allowed. Please apply the $50 extra claim fee, any credits or additional charges, to deposit account 06-1050.

Respectfully submitted,

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